REMARKS

In response to the Office Action mailed October 20, 2006, reconsideration of the application is respectfully requested in view of the pending claims and the following remarks.

I. THE PENDING CLAIMS

Claims 1 and 53-55, and 57-69, of which claims 1 and 67 are independent, remain pending. Claims 2-52 and 56 are cancelled. New claims 70 and 71 are added. No new matter has been introduced by the amendments presented herein.

By this amendment, Applicants have amended claims 1 and 67 by incorporating the phrase "and wherein the capillary matrix is composed of a material different from the material comprising the lateral flow chromatography strip" at line 5 and line 11 of each of the respective claims. In addition, the recited elements of claim 56, *i.e.*, "wherein the lateral flow chromatography strip contains at least one reagent that is used to detect or quantify at least one analyte in the oral fluid" have been inserted into independent claims 1 and 67, thereby canceling claim 56.

Additional amendments of the pending claims are as follows:

(i) In claim 1, the phrase "a housing" has been inserted after the term "comprising;" the phrase "extending from within the housing and protruding out from the housing" has been incorporated after the recited phrase "capillary matrix;" the phrase "having an exposed surface" has been deleted; the phrase "within the housing" has been added after the recited phrases "chromatography strip" (first occurrence) and "blocking strip;" the term "contains" has been substituted by the phrase "is impregnated with;"

(ii) In claim 53, the phrase "a chelating agent" has been inserted after the term "detergent;"

(iii) In claim 54, the claim dependency has been changed from claim 53 to claim 1;

(iv) In claim 55, the phrase "within the housing" has been added after the recited phrase "conjugated strip;"

(v) In claim 63, the phrase "further comprising" and the term "having" have been deleted and the phrase "wherein the" and the term "contains" have been added into the claim;

(vi) In claim 65, the phrase "within the housing" has been incorporated at line 2 and the phrase "a housing having a cavity has been incorporated in claim 1 and is, therefore, deleted in the claim;

(vii) In claim 66, the term "flow" has been inserted before the term "communication;" and

(viii) In claim 67, the recited phrase "a housing having a cavity" has been moved up to line 3 of the claim; the phrase "extending from within the housing and being substantially exposed outside the housing" has been incorporated after the recited phrase "capillary matrix;' the phrase "having exposed surface" has been deleted; the phrase "within the housing and" has been added after the recited phrases "blocking pad," "conjugate pad," and "chromatography strip" (third occurrence); the term "contains" has been replaced by the phrase "is impregnated with;" and the phrase "wherein the lateral chromatography extends into the cavity along...at selected sites on the lateral flow chromatography strip," located at the end of the claim, has been added into the recited "lateral flow chromatography strip" (third occurrence).

New claim 70 recites "a chelating agent," *e.g.*, "EDTA" and new claim 71 recites blocking agents such as bovine serum albumin, deoxycholate, and n-lauroyl sarcosine and a chelating agent, *e.g.*, EDTA, respectively.

Support for all of the amendments and the addition of new claims can be found at least on, *e.g.*, p. 4, ll. 6-8; p. 5, ll. 24-26; p. 10, ll. 15-17; p. 20, ll. 5-7; p. 21, ll. 16-18; p. 22, ll. 14-16; and p. 20, l. 1-7; p. 20, l. 29-p. 22, l. 19 of the specification, as well as Figures 1-3.

To remove minor clerical errors and provide clarity, Applicants have revised claim 57 by (1) deleting the phrase "at least" at line 1 of the claim; (2) after the term "IGA," a comma (,) is inserted and the term "and" is deleted; and (3) the phrase "and other analytes including" and the term "cholesterol" are deleted at line 11 of the claim. Support for these amendments can be found at least on, *e.g.*, p. 10, ll. 15-17, of the specification. In addition, claim 61 has been revised by insertion of a hyphen between the terms "paddle" and "shaped."

Applicants respectfully submit that the rejections based on indefiniteness, obviousness and non-statutory obviousness-type double patenting are overcome in view of the amendments and arguments presented herewith.

II. CLAIM REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

In the Office Action, the Examiner rejected claims 57-59 under 35 U.S.C. § 112, second paragraph, as allegedly being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." According to the Examiner, claims 57-59 are indefinite on the ground that the recited "analytes cannot be part of the device of claim 56 since these analytes are collected at the time of the assay." Applicants respectfully traverse the rejection.

To overcome the rejection, Applicants have amended claim 57 by deleting phrases, such as "at least" and "and other analytes including." In view of these amendments, Applicants respectfully submit that these claims are no longer indefinite thereby rendering the rejection moot. Reconsideration and withdrawal of the §112, ¶2 rejection of claim 57, as well as its dependent claims 58 and 59, are, therefore, earnestly requested.

III. REJECTIONS UNDER 35 U.S.C. § 103(a)

A. Rejection of claims 1 and 53-69 over May, in view of Schlipfenbacher

Claims 1 and 53-69 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U. S. Patent No. 5,622,871 to May *et al.* (hereinafter "May"), in view of U. S. Patent No. 5,160,486 to Schlipfenbacher *et al.* (hereinafter "Schlipfenbacher"). In particular, the Examiner asserted that "May discloses a device comprising a housing and a strip, the strip comprising a collection strip in fluid communication with a lateral flow assay strip, wherein the lateral flow assay strip, also being an immunochromatography strip, is contained substantially within the housing, contains at least one blocking reagent or buffer, contains at least one reagent used to detect the presence or absence of an antibody, and contains one or more zones that indicate the presence or absence of the antibody." In addition, the collection strip, according to the Examiner, comprises "a capillary matrix adapted for rapid wicking of fluid from a source to the assay strip." Regarding claim 61, the Examiner stated that "the collection strip protrudes from the housing and is a paddle-shape" and the reagent is "a binding partner that bears a detectable label." With respect to claims 57-59, the Examiner considered these claims as failing to "further structurally limit the claimed device and instead relate to "analytes which are not part of the device." Regarding claims 68 and 69, the Examiner contended that May discloses "a kit comprising the device discussed above and separately a buffer or reagent."

May, however, as noted by the Examiner, "differs from the instant claimed invention in failing to teach a blocking strip and conjugate strip between the collection strip and assay strip." To cure this deficiency, the Examiner cites Schlipfenbacher which, according to the Examiner, discloses "a blocking strip containing a buffer and a conjugate strip between the collection strip and assay strip."

Applicants respectfully traverse this rejection since May and Schlipfenbacher, either individually or in combination, fail to describe the features set forth in independent claims 1 and 67, as well as the rejected claims depending therefrom.

As set forth in amended independent claim 1, the present invention relates to an apparatus for collection and lateral flow chromatography of an oral fluid that comprises the following features, namely, a housing having a cavity (*see* specification at p. 5, l. 13-18 and pp. 21-22); a capillary matrix extending from within the housing and protruding out from the housing for receiving oral fluid (*see* specification at p. 3, ll. 17-31, 5, l. 20-26, p. 21, ll. 16-18, p. 22, ll. 13-16); a lateral flow chromatography strip within the housing, wherein the lateral flow chromatography strip contains at least one reagent that is used to detect or quantify at least one analyte in the oral fluid and is in flow communication with the capillary matrix and wherein the capillary matrix is composed of a material different from the material comprising the lateral flow chromatography strip (*see* specification at p. 4, ll. 6-8, p. 17, l. 8-p.19, l. 21, and pp. 21-22); and a blocking strip within the housing, coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip is impregnated with at least one blocking agent (*see* specification at p. 5, ll. 5-9, p. 19, l. 25-p. 20, l. 14, and p 21).

Amended independent claim 67, besides reciting all the elements of amended claim 1, also includes (1) a conjugate pad within the housing that contains lateral flow chromatography reagents and is coupled between the blocking pad and the lateral flow chromatography strip (*see* specification at p. 5, ll. 10-12, p. 20, ll. 16-27 and p. 21), and (2) at least one inspection site from an exterior of the housing to the lateral flow chromatography strip to help in visualization of the test outcome (*see* specification at p. 5, ll. 13-18 and pp. 21-22).

As illustrated in the specification at pages 21-22 and Figures 1 and 3 (see below), the claimed apparatus comprises a lateral flow chromatography strip (C) that us disposed lengthwise within the housing (H). One end of the chromatography strip (C) contacts directly,

or by way of blocking pad (B) with a portion of capillary matrix (W). The capillary matrix (W) projects out of the housing (H) where it presents a face (3) that acts as an absorbent surface for uptake of oral fluid. The oral fluid migrates through the matrix (W) and through the blocking pad (B), where it is finally delivered to a receiving area (R) on the lateral flow chromatography strip (C). The oral fluid then migrates along the lateral flow chromatography strip (C) where it interacts with various reagents that are deposited within the chromatography strip (C) and/or within optional conjugate strip (G), which, when present, contacts the chromatography strip (C).

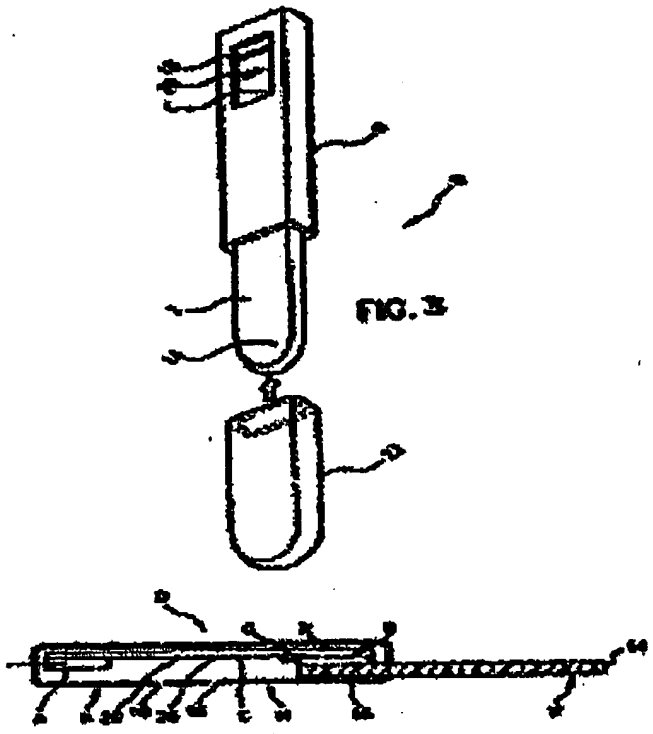


FIG. 1

The claimed invention, as recited in amended claims 1 and 67, is distinct from May. This is because May neither discloses nor suggests a blocking strip that is impregnated with at least one blocking reagent and or a conjugate strip that contains lateral flow

chromatography reagents. May's device does not include a lateral flow chromatography strip that contains at least one reagent that is used to detect or quantify at least one analyte in the oral fluid and wherein the capillary matrix is composed of a material different from the material comprising the lateral flow chromatography strip. Accordingly, Applicants respectfully submit that May fails to anticipate and render obvious independent claims 1 and 67, particularly in light of the additional remarks provided hereinbelow.

Contrary to the claimed invention, May discloses a test device for detecting an analyte in a liquid biological sample that includes a hollow casing containing a dry porous carrier, which communicates directly or indirectly with the exterior of the casing via a bibulous porous receiving member that protrudes from the casing and acts as a reservoir from which the liquid biological sample can be applied to the porous carrier. The porous carrier, in turn, contains (1) in a first zone, a labeled specific binding reagent that is freely mobile within the porous carrier when in the moist state, and in (2) in a second zone, spatially distinct from the first zone, a permanently-immobilized unlabelled specific binding reagent for the same analyte. May's device also includes a liquid biological sample aperture in the hollow casing as a means for viewing the test result.

Schlipfenbacher, on the other hand, discloses a test carrier for analyzing sample liquid that includes a plurality of capillary action test zones arranged on a base layer that is in liquid contact with one another. These test zones are arranged in a particular order, namely, a sample application zone (start zone) where a first specific binding partner is applied, auxiliary zone that contains blocking reagents or buffers; a conjugate zone containing a labeled conjugate of the first and a second specific binding partner; a fixing zone wherein the first binding partner competes with the labeled conjugate of the first binding partner competes for binding to the second binding partner being carrier-fixed; and a detection zone to detect the labeled species. As provided by Schlipfenbacher, the material that comprise the test zones are made of at least 50% of the non-swelling fiber fleece materials, such as polyamides and polyesters as well as mixtures thereof, in combination with the fibers of polyvinylalcohol. Contrary to Schlipfenbacher, the claimed apparatus include a capillary matrix that comprises a porous plastic material while the lateral flow chromatography strip is from paper or nitrocellulose. Therefore, the claimed apparatus includes a lateral flow chromatography strip that wherein the capillary matrix is composed of a material different from that of the lateral

flow chromatography strip.

Based on these foregoing reasons, one of ordinary skilled in the art would not be motivated to combine the device of Schlipfenbacher and with the device of May with an expectation of successfully arriving at Applicants' claimed invention. Applicants respectfully submit that May and Schlipfenbacher, alone or in combination, fail to render these claims obvious. *See* MPEP §2143.03 ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art"). As shown by the remarks above, Applicants respectfully submit that the Examiner has failed to establish the *prima facie* obviousness of claims 1 and 53-69. Reconsideration and withdrawal of the §103(a) rejection of these claims is, therefore, earnestly requested.

B. Rejection of claims 1, 53-58, 60-65 and 67-69 over Moorman, in view of Ching

Claims 1, 53-58, 60-65 and 67-69 under 35 U.S.C. §103(a) as being unpatentable over U. S. Patent No. 5,820,826 to Moorman (hereinafter "Moorman"), in view of U. S. Patent No. 5,120,643 to Ching *et al.* (hereinafter "Ching").

In rejecting these claims, the Examiner considered the blocking strip of the presently claimed invention as being equivalent to Moorman's blocking strip. This reasoning is based on Moorman's disclosure of the use of two double-sided tapes "to block the flow of the fluid, *i.e.*, a blocking strip, and the one way flow regulating means, in addition to its functions as a blocking means, may also contain reagents such as buffers (column 11, lines 12-21 and lines 49-51)." The Examiner asserted that the "instant claims do not specifically define the blocking strip" and "requires only that it contains at least one blocking agent and is disposed between a sample collection matrix and a chromatography strip" and, therefore, "such a strip is clearly taught by Moorman."

Besides the blocking strip, the Examiner also considered Moorman's sponge (identified as zone 26 in Figure 2) is equivalent to the claimed capillary matrix that "functions as a sample application area," which "must have an exposed surface, otherwise fluid cannot be applied to it."

Applicants respectfully traverse this rejection.

Applicants respectfully submit that the Examiner, upon the examination of the

pending claims, must give these claims the broadest reasonable interpretation consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969). When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As set forth in p. 19 line 1 – p. 20, l. 7, of the specification, the blocking strip is "a strip between the porous matrix and the lateral flow chromatography strip" that (1) "can be impregnated with buffers to adjust the pH of the oral fluid for compatibility with the lateral flow chromatography assay" and (2) "can include one or more blocking reagents that reduce non-specific binding of the analyte and/or reagents of the assay device thereby reduce the occurrence of false positives." The specification further provides the materials that make up the blocking strip or pad (*see* p. 20, ll.1-2) and examples of blocking reagents, such as bovine serum albumin, deoxycholate and n-lauroyl-sarcosine, as well as the compositions of two blocking solutions (*see* p. 20, ll. 2-7). Thus, as disclosed, the specification is "the primary basis for construing the claims" (citing *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985)). Accordingly, contrary to the Examiner's contentions, Moorman's blocking strip, whose function is to "block the liquid from going forward, forcing it to move down and into the substrate pad and, therefore, establishing a predefined channel for directional fluid flow through the structure pad (component 27, *see* Moorman at col. 10, ll. 59- 67), cannot be equivalent with the claimed blocking strip of the present invention. Furthermore, Moorman's examples of blocking material include the double stick tapes and hardened hot melted adhesives.

Moorman's absorptive means, structure 26, comprising absorptive material for application of a fluid thereto (*see* Moorman at col. 10, ll. 22-23) does not correspond to the claimed capillary matrix of the present invention. As set forth in Moorman, absorptive means 26 is positioned above the substrate pad (structure 27) to "allow the moistening agent" or "run buffer" to be applied into it. By using the double stick tapes (28 and 28'), the fluid can only go into the front end of the substrate pad and, at the same time, forcing the fluid to move downward into the substrate pad (lateral flow chromatography strip). (*see* Moorman at col. 10, l. 46-54). The materials that constitute Moorman's structures 26 and 27 are limited only by the requirement that they be absorbent and inert relative to the reagents which contact

them. An example of such absorbent material is a sponge. Contrary to Moorman's absorptive means, the claimed capillary matrix is not positioned above the lateral flow chromatography strip. Instead, it lies next to the lateral flow chromatography strip and is in direct communication to the strip. The flow of the oral fluid would be forward and not downward as Moorman. More importantly, the materials that comprise the claimed capillary matrix and lateral flow chromatography strip, as recited in amended independent claims 1 and 67, are different from each other. Also of importance is that the capillary matrix of the present invention is a hydrophilic porous plastic matrix that is "essentially non-absorbing" but adsorbs (instead of absorbing liquid as taught and suggested by Moorman) liquid via capillary action and delivers the oral fluid the lateral flow chromatography strip. (*See* p. 5, ¶ 0055, ll. 1-3 and p. 4, ¶0044, ll. 6-9). Moreover, claimed capillary matrix, as disclosed in the specification, at p. 6, ¶0063, ll. 4-7, "acts more as a conduit than as an absorbent; material is readily discharged from the wick."

In addition to the above-mentioned differences, Moorman fails to disclose or suggest the claimed apparatus for collection and lateral flow chromatography of oral fluids wherein the lateral flow chromatography strip contains at least one reagent that is used to detect or quantify at least one analyte in the oral fluid.

In the Office Action, at p. 5, ¶1, the Examiner acknowledged that Moorman is deficient with respect to the disclosure of blocking agents. However, this deficiency, according to the Examiner, can be found in the secondary reference. Ching, as asserted by the Examiner, discloses "devices using labeled specific binding materials including colloidal particle and enzyme labeled materials which are dried onto a chromatographic medium in the presence of a meta-soluble protein..." and "impregnating solid substrate materials with meta-soluble proteins such as bovine serum albumin and detergents, *e.g.*, sodium deoxycholate, *etc.*"

In view of Ching, the Examiner concluded that it would have been obvious to one of ordinary skill in the art to "add the meta-soluble proteins as taught by Ching to the blocking means or substrate pad of Moorman because additional features may be incorporated into the apparatus including antibodies, signal inhibitors, buffers and so forth." In addition, Ching, according to the Examiner, "teaches that improved assay results is achieved using the meta-soluble agents." The Examiner further concluded that "a skilled artisan would have had a

reasonable expectation of success" when adding Ching's meta-soluble agents to Moorman's device because Moorman has indicated that "the addition of agents such as buffers and the like are well known in the art" and "the choice of appropriate agents is chosen on the basis of the aim of the assay and the type of analytes."

Applicants respectfully submit that Ching, like Moorman, fails to disclose or suggest the claimed apparatus for collection and lateral flow chromatography of oral fluids that comprises the features of claims 1, 53-58, 60-65 and 67-69. In particular, Ching is completely silent with respect to the claimed lateral flow chromatography strip and blocking strip or pad that contains blocking agents, as recited in the above-mentioned claims. Ching cannot remedy the deficiencies of Moorman, as discussed above. One of ordinary skill in the art would not be motivated to combine both Moorman and Ching or have any reasonable expectation of success to arrive at the claimed invention.

Based on the above-mentioned remarks and amendments, Applicants respectfully submit that Moorman and Ching, either individually or in combination does not anticipate nor render obvious claims 1, 53-58, 60-65 and 67-69. Applicants respectfully request the reconsideration and withdrawal of this rejection and the allowance of these claims.

C. Rejection of claim 59 over Moorman, in view of Ziegelmaier

At pages 6-7 of the Office Action, the Examiner rejected claim 59 under 35 U.S.C. §103(a) as being unpatentable over Moorman, in view of U. S. Patent No. 6,632,628, to Ziegelmaier *et al.* (hereinafter "Ziegelmaier"). According to the Examiner, Moorman, who "differs from the instant claims in failing to teach the detection of hepatitis," "does teach that the analyte and the analyte specific receptors are chosen on the basis of the aim of the assay and discloses typical tests including assays for etiological agents for infectious diseases." However, Moorman's deficiency, as asserted by the Examiner, can be cured by Ziegelmaier, who's claimed invention is directed to "assays for etiological agents for infectious diseases such as HIV, rubella, hepatitis A and B, *etc.*" Applicants respectfully traverse this rejection.

Ziegelmaier does teach a one-step immunoassay for the determination of antigen-specific antibodies directed against the above-mentioned infectious diseases. Like all of the above-mentioned references, Ziegelmaier also fails to disclose or suggest the claimed apparatus for detecting at least one analyte that is an antibody to hepatitis. More particularly, Ziegelmaier fails to cure the deficiency of Moorman as a primary reference. As remarked

above, Moorman is not a patent-defeating reference with respect to the subject matter of claim 59. Accordingly, Moorman and Ziegelmaier neither disclose nor suggest elements of claim 59. Applicants respectfully submit that both Moorman and Ziegelmaier do not render claim 59 obvious. .

D. Rejection of claims 1, 53, 55-58, 60-61 and 63-69 over Kremer, in view of Sangha and de Zoeten.

Claims 1, 53, 55-58, 60-61 and 63-69 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U. S. Patent No. 4,635,488 to Kremer *et al.* (hereinafter "Kremer"), in view of U. S. Patent No. 5,334,502 to Sangha *et al.* (hereinafter "Sangha") and U. S. Patent No. 5,611,995 to de Zoeten (hereinafter "de Zoeten").

At page 10 of the Office action, the Examiner stated that "Kremer differs from the instant claims in failing to teach that the blocking strip comprises blocking agents and detergents or buffers." Such deficiency by Kremer, however, can be cured by Sangha and De Zoeten, both of which, according to the Examiner, discloses (1) a test card for detecting analytes in a saliva sample comprising tretramethylbenzidine (TMB) dissolved in dimethyl formamide (DMF) or dimethyl sulfoxide (DMSO) and EDTA impregnated thereon and dried" and (2) "conventional blocking agents such as polyvinylalcohol, or human and bovine serum albumin," respectively.

Based on the combined teachings of Kremer, Sangha, and De Zoeten, the Examiner concluded that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to place reagents such as buffers and detergent taught by Sangha and de Zoeten in the device of Kremer because Sangha and de Zoeten teach that such reagents are well known in the art as providing the advantage of improving assay results by maintaining appropriate pH of the sample and dissolving interference material prior to contacting the sample with the test reagents. A skilled artisan would have had a reasonable expectation of success in placing these reagents on the strip of Kremer because Sangha teaches a blocking strip made of the same material as that of Kremer which can incorporate reagents such as dyes, and de Zoeten teaches adding buffering compounds to a sample collector (also made of the same material) to adjust pH of the test liquid and therefore, absent unexpected results, these limitations are seen to be obvious in view of the teachings of Kremer as modified by Sangha and de Zoeten." Applicants respectfully traverse this rejection.

Kremer discloses a sampling device that includes a hollow tube having "at least one open end, and a collecting nib secured in that open end of the tube and having an inner extremity facing the interior of the tube and an outer tip projecting beyond the last mentioned end of the tube for contact with a fluid (*e.g.*, sweat, tears or saliva) to be collected" (col. 2, ll. 49-55). The nib comprises a solid, nonfibrous, porous, water-wettable body having porosity sufficient for absorption of the fluid to be collected (col. 2, ll. 55-57). Based upon Kremer's disclosure, a sampling device having a hollow tube with one cap and one open end is used for collecting body sample fluids. On the other hand, a sampling device having a further cap (structure 16) for closing the second open end (structure 18), as disclosed by Kremer, is used not only for sample collect but also for sample analysis since the hollow tube is in direct contact with an analysis element (structure 44 (strip) or structure 46 (column)). The analysis element incorporates an agent which undergoes an observable change upon contact with a substance to be detected (col. 6, ll. 44-50 and can be removed from the hollow tube after absorbing the sample, for subsequent analysis (col. 3, ll. 56-58).

In addition, a "nib" as defined in the Webster's College Dictionary, 2000, at p. 893, col. 1, refers to (a) "a penpoint or one of the two segments of a split penpoint;" or (b) "any pointed end." As illustrated in Figures 1 and 6 of Kremer, the collecting nib (12), as well as its exposed tip (28) does not correspond to and is distinct from the claimed capillary matrix (W) or (3), as illustrated in Figures 1 and 3, respectively, of the specification (*see supra*). The claimed capillary matrix, as recited in amended claims 1 and 67, "projects out of" or "protrudes from" "the housing" to "provide a planar surface" for receiving oral fluid (*see* specification at p. 21, ll. 16-18 and p. 22, ll. 14-16).

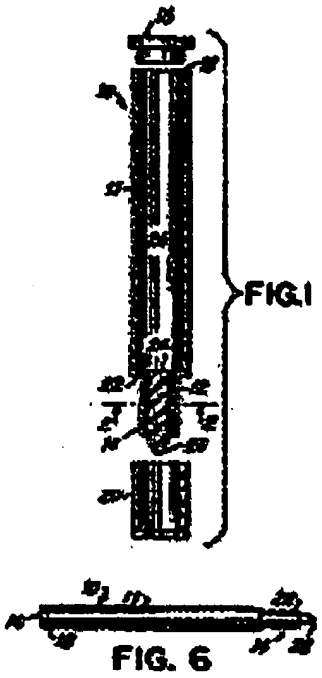


FIG. 6

In addition, the claimed lateral flow chromatography strip is enclosed inside the housing and is in direct contact with the capillary matrix. In Kremer, the analysis element for sample detection is a removable portion of the sampling device, quite the opposite of what is being set forth in the claimed invention. In addition, the lateral flow chromatography strip of the claimed invention contains at least one reagent for use in detecting or quantifying at least one analyte in the oral fluid. Such disclosure is absent in Kremer. Also absent is the presence of the blocking strip or pad that contains at least one blocking agent, as acknowledged by the Examiner in the Office Action. With respect to claim 67, Kremer fails to disclose or suggest a conjugate strip that is coupled between the blocking strip and lateral flow chromatography strip.

Sangha discloses a method and device for collecting and identifying saliva for analysis and sample verification. The method comprises obtaining a saliva sample from a subject using a sample probe and application of the sample to an absorbent sheet or layer.

The sample probe is composed of support stick having swab for sample collection (col.5, ll. 44-48). An example of the sample probe, as provided by Sangha and also cited by the Examiner in the Office Action (p. 9), is presented in Figure 8. As shown, a capillary tube 78 surrounds absorbent 80 and on top of absorbent 80 is one-way barrier 82 containing indicator component 84. As saliva migrates or is wicked along absorbent 80, it approaches barrier 82, which is situated atop absorbent 80. The saliva will pass through one way barrier 82 to interact with indicator component 84. The indicator component can be either a vegetable dye or a colorless substrate which act as a chromogen in the presence of saliva. The Examiner asserted that Sangha also discloses "a test card for detecting the saliva sample (col. 15, ll. 13-27).

Similar to Kremer, Sangha fails to disclose the claimed apparatus as set forth in claims 1 and 67 of the present invention. Sangha is silent with respect to the claimed lateral chromatography strip and blocking strip, as well as the conjugate strip with respect to claim 67. There is no suggestion or motivation to combine both of Kremer's and Sangha's teachings for one of ordinary skill in the art to arrive at the claimed invention.

De Zoeten discloses an apparatus having a housing and holding device (can be separable from the housing) for holding a test strip comprising a sample collector which can readily absorb test liquid, but also easily release the liquid under capillary transfer. According to De Zoeten, the transfer of the liquid sample from the sample collector to the test strip can be achieved by simply pressing or indirectly by capillary means using a connector (col. 4, ll. 34-49). This is contrary to the claimed invention where transport of the oral fluid to the lateral chromatography strip is accomplished without any manipulation or compression of the matrix material itself (see specification at p. 12, l. 1 - p. 13, l.2). De Zoeten does teach the use of a nitrocellulose test strip that is directly coupled with antibodies without a previous chemical treatment on the test strip. After coupling, however, the remaining binding sites on the same test strip should be blocked by treating the test strip with hydrophilic synthetic polymers such as polyvinylalcohol or hydrophilic biopolymers such as bovine serum albumin or ovalbumin (col. 7, ll. 5-11). This is distinctly different from the claimed apparatus of the present invention where a separate blocking strip or pad is provided and is coupled between the capillary matrix and lateral flow chromatography strip. Accordingly, De Zoeten is not a patent-defeating reference to the presently claimed invention.

None of these references, Kremer, Sangha and De Zoeten, either alone or in combination, suggests an apparatus for collection and lateral flow chromatography of oral fluid, in particular, the claimed features of the lateral flow chromatographic strip, a blocking strip coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip contains at least one blocking agent. Therefore, Applicants respectfully submit that Kremer, Sangha and De Zoeten, either individually or in combination do not render obvious 1, 53, 55-58, 60-61 and 63-69. *See* MPEP §2143.03 ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.").

Moreover, Applicants respectfully submit that the Office Action has failed to establish a motivation to combine the primary reference and secondary references as suggested by the Examiner. There is no reasonable expectation of success either. The Federal Circuit has repeatedly emphasized that evidence of a motivation to combine must accompany a challenge based on multiple references. *See In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999) and *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed. Cir. 1998). *See also* MPEP §2143.01 (The prior art must suggest the desirability of the claimed invention). A mere statement, that the combination of the prior art meets the claimed invention and would have been within the ordinary skill in the art, is not alone sufficient to establish a *prima facie* case of obviousness. *See* MPEP §2143.01.

Based on the above reasons, Applicants respectfully submit that the Examiner has failed to establish the *prima facie* obviousness of claims 1, 53, 55-58, 60-61 and 63-69. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §103(a) rejection of these claims.

E. Rejection of claim 62 over Kremer or Moorman, in view of Sangha and de Zoeten, as applied to claims 1, 53, 55-58, 60-61 and 63-69, and further in view of Porex Technologies Catalog, 1995

At page 11 of the Office Action, the Examiner rejected claim 62 under 35 U.S.C. 103(a) as being unpatentable over Kremer or Moorman, in view of Sangha and de Zoeten, as applied to claims 1, 53, 55-58, 60-61 and 63-69, and further in view of Porex Technologies Catalog, 1995. The Examiner acknowledged that Kremer, Moorman, Sangha and de Zoeten fail to "teach a capillary matrix having an average pore size from about 40 to 250μm. The

deficiency found in all these references, according to the Examiner, however, is cured by Porex's disclosure of porous plastics available in molded shapes, sheets, rods and tubes having an average pore size from 7 to greater than 250 micrometers. The Examiner further asserted that "Porex engineers can also develop custom designs for specific use which will take into consideration strength, sample flow, durability and shape." Based on these assertions, the Examiner concluded that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to choose a porous nib with the desired pore size such as taught by Porex for use in the device of Kremer or Moorman, as modified by Sangha and de Zoeten because these parameters are dependent on the nature of the assay, *i.e.*, samples to be tested and reagents involved." The Examiner further asserted that a skilled artisan would have had a reasonable expectation of success in choosing from any of the disclosed nibs or to have nibs specification made to fit their needs. According to the Examiner, "the selection of a specific material is generally dependent on the assay and the characteristics of the sample, therefore, absent unexpected or improved results, selection of nibs with specific pore sizes so as to optimize the performance of a device is seen to be obvious in view of the teachings of Kremer or Moorman and Porex Technologies." Applicants respectfully traverse this rejection.

As remarked earlier and in light of the amendments presented hereinabove, Applicants respectfully submit that Kremer, Moorman, Sangha, or de Zoeten, either alone or in combination, fails to teach the subject matter of claim 1 and its dependent claim 62. In addition, the Porex Technologies Catalog, as cited by the Examiner, also fails to cure the combined deficiencies of these references. Applicants respectfully submit that Kremer, Moorman, Sangha, de Zoeten and the Porex Technologies Catalog all fail to render obvious claim 1 and its dependent claim 62. *See* MPEP §2143.03 ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.").

Moreover, Applicants respectfully submit that the Examiner has failed to provide any reasonable expectation of success to arrive at the claimed invention. In addition, the Examiner also fails to establish a motivation to combine Kremer, Moorman, Sangha, de Zoeten and the Porex Technologies Catalog. The Federal Circuit has repeatedly emphasized that evidence of a motivation to combine must accompany a challenge based on multiple

references. *See In re Dembiczak,* 175 F.3d 994 (Fed. Cir. 1999) and *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed. Cir. 1998). *See also* MPEP §2143.01 (The prior art must suggest the desirability of the claimed invention). A mere statement, that the combination of the prior art meets the claimed invention and would have been within the ordinary skill in the art, is not alone sufficient to establish a *prima facie* case of obviousness. *See* MPEP §2143.01.

Based on the above reasons, Applicants respectfully submit that the Examiner has failed to establish the *prima facie* obviousness of claims 1 and 53-69. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §103(a) rejection of these claims.

IV. NON-STATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

On page 12 of the Office Action, the Examiner provisionally rejected claims 1, 53, 55-61 and 63-69 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 67-80 and 51-53 of co-pending Application No. 09/973,956, which issued today as U.S. Patent No. 7,192,555 B2.

To the extent that this rejection applies to the pending claims, Applicants request that this rejection be held in abeyance until are indicated to be allowable.

Finally, Applicants respectfully submit that all of the §§112, ¶2, 103(a) and non-statutory obviousness-type double patenting rejections of the pending claims have been overcome. Reconsideration and withdrawal of these rejections are earnestly requested.

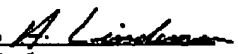
CONCLUSION

For at least the reasons set forth above, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. A fee for extension of time for two (2) months is due for filing this response. The Commissioner is hereby authorized to charge any payment deficiency to Deposit Account No. 19-2380 referring to Docket No. 030793-036100.

Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicants' representative designated below.

Respectfully submitted,

Date: March 20, 2007



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